Nevada Medicaid
Pharmacy & Therapeutics Committee

Location of Meeting
401 South Carson Street, Room 3137, Carson City, NV

Teleconference
555 E. Washington Avenue, Room 4401, Las Vegas, NV

MEETING MINUTES OF
October 28, 2004

Committee Members Carson City:
Steven Phillips, MD**,** Chairman
Carl Heard, MD
Susan Pintar, MD
Thomas Wiser, Pharm.D.

Committee Members Las Vegas:
Robert Horne, MD
Larry Pinson, Pharm.D. (Late)

Absent:
Judy Britt, Pharm.D., Linda Flynn, R.Ph., Alan Greenberg, MD, Diana Bond, R.Ph.

Others Present:
Carson City:
Darrell Faircloth AGO, Coleen Lawrence DHCFP, Nancy Davis DHCFP, Jeff Monaghan Pharm.D. First Health Services Corporation, Shirley Hunting First Health Services Corporation, Randy Dossat Roche, Ken Romeo Roche, David Abrahamson Merck, Bert Jones GSK, Kara Smith BI, Bruce Martz BI, Laurie Squartsoff Eli Lilly, Kelly Wright Amgen, Steven Spadaro Pfizer, Gary Comstock Pfizer, Joann Phillips, Kathy Phillips Merck, Jake Mater Aventis, Jim Morgan Norvartis, Tom Wood PhRMA

Las Vegas:
Carla Sloan Advisory Committee, Jamie Wyels First Health Services, Paul Pereira Tap, Sedrick Spencer Roche, Alan Sloan Purdue, Roland Baldwin Wyeth, Joe Duarte Cephalon, Bob Ulmer Proctor & Gamble, Megan Bender Nevada Care, Lynn Nagorski Purdue, C. James Pfizer.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1:24p.m. Committee members present in Las Vegas: Robert Horne, MD, Larry Pinson, Pharm.D. (late); Carson City: Steven Phillips, MD, Carl Heard, MD, Susan Pintar, MD, Thomas Wiser, MD.

II. *Review and Approval of July 14th and August 12th Meeting Minutes

Correction to Minutes:

Dr. Horne: page 13, paragraph 5, change children 6-8 to children 6-18

Dr. Phillips: page 13, discussion paragraph following Judy Britt's motion, change fluvoxamine to fluoxetine.

Page 6, Dr. Greenberg's request following motion, change cellulites to cellulitis.

Dr. Phillips requested Dr. Monaghan address action items contained within the minutes which required follow-up.

Dr. Monaghan addressed the following:

Item XII: Quinolones Second Generation
Ms. Flynn raised the issue: is the PDL in conflict with pharmacy law specifically as it relates to the requirement to dispense a generic versus a brand name drug?

Dr. Monaghan consulted with Keith Macdonald and Louis Ling of the State Board of Pharmacy. They stated that as the payor, the least expensive agent is being dispensed and is not in conflict with state pharmacy law.

Item XIII: Onychomycosis Agents
Dr. Greenberg asked for the DUR board to consider another indication: recurrent cellulitis.

Dr. Monaghan: This item is on the agenda for the December DUR board meeting.

Item XX: Nasal Steroids
Dr. Heard motioned to accept this class as recommended but asked for an aqueous solution alternative.

Dr. Monaghan: Nasonex, an aqueous product, was added to the list.

Item XXX: New Generation Antidepressants
Coleen Lawrence commented on grandfathering allowing titration of drugs in the coding.

Dr. Monaghan: dosage change is allowed without obtaining another PA.

Item XXXI: Stimulants/ADHD Drugs
Dr. Horne requested Provigil be placed on the agenda for the October meeting and also that the PA criteria for the CNS stimulants be reconsidered by the DUR Board.

Dr. Monaghan: Provigil is included on the agenda for the October meeting.
The DUR Board has reconsidered and decided to maintain the current edits and expanded that to include Strattera. Presentation at one more public hearing is required prior to implementation.

Dr. Horne: does that mean they want to require an IQ test on every adult with attention deficit hyperactivity disorder before they can get any medication?

Dr. Monaghan suggested Dr. Horne draft a letter to the chairman of the DUR Board addressing his concerns and forward the letter to Coleen Lawrence, DHCFP, for presentation to the DUR Board.

Item XXXIII: Public Comment
Tom Wood, PhRMA, requested clarification from the attorney general's office on the role of the DUR Board and P&T Committee.

Deputy Attorney General, Darrel Faircloth, stated that he preferred that the attorney general opinion be agendized for presentation at a future meeting, if needed.

Per Dr. Phillips, the opinion was sent to the Committee by Mr. Duarte, DHCPF, and received by Dr. Phillips. Ms. Lawrence stated the same letter, which gives an overview of the opinion, was presented to the DUR Board and read into record.

Item V: Proton Pump Inhibitors
Dr. Monaghan: The duration of approval for chronic GERD has been extended. PA's are now approved for 12 months versus 90 days.

Public Comment:
Tom Wood, PhRMA: On the attorney general's opinion, do you care to wait?
Dr. Phillips: Yes

Dr. Pinson joined the Committee at 1:49 p.m.

Motion: Dr. Pintar moved to approve the minutes of July 14th and August 12th as corrected.
Seconded: Dr. Wiser
Ayes: Unanimous
Motion Carried

III. Report on Preferred Drug List Implementation - First Health Services

Dr. Monaghan presented a status report on the PDL implementation to date (attached). He stated that this implementation has been one of the smoothest, most effective rollouts for FHSC and complemented the Committee for their efforts.

Dr. Monaghan stated that one way to measure success is by the number of calls the clinical call center receives from providers asking for exceptions to the PDL. During the 8 week period beginning September 1, 1,348 or 50 requests per day were received. New Hampshire, which closely mirrors Nevada's recipient count and volume, experienced 400-500 calls per day. The approval rate (authorization for non-PDL agent) was 45%. The average approval rate in other states is 85%. After provider dialog with the clinical pharmacist, the change rate (request changed to a preferred agent) was 55%. Drugs most commonly changed to a non-preferred agent are antihistamines (most requested), proton pump inhibitors, sedative hypnotics, ace inhibitors, beta-adrenergic agents and beta blockers. These agents comprise 60% of the requests.

Dr. Monaghan addressed concerns expressed by the pharmaceutical industry regarding the implementation. He stated that specific examples researched indicate the mechanics are in place and the system is doing what it's designed to do. He extended an invitation to address any concerns noting that due to HIPPA requirements, inquiries regarding specific patients must be submitted by the prescriber.

Dr. Heard stated that it is encouraging that there hasn't been a whole wash of issues and expressed his appreciation to Dr. Monaghan for making this a smooth transition.

Dr. Wiser: the numerator was given, what is the denominator?

Dr. Monaghan: The denominator is approximately 6,000 fee-for-service claims per day. 0.8% of the claims are generating calls regarding the PDL. 50-60% of the 6,000 claims are affected by the PDL. The average time per call is 5 minutes.

Dr. Heard stated he would like to continue to watch this and receive reports in the future.

Dr. Horne expressed concern regarding patients discharged from the State hospital on a non-preferred medication. He asked if there is a way to develop a mechanism that if a patient has failed a preferred medication, they could continue on the drug they received and responded to in the hospital.

Dr. Monaghan stated that payment history is considered. The call center will accept medical documentation indicating the patient has received the medication from a source outside of the Medicaid payment system and it should be approved.

Dr. Heard suggested that if a patient is being discharged from a mental health facility and is being discharged on a mental health drug, we accept the physician's word and apply the six month or year grace period for certain psych drugs while the patient is transitioned.

Coleen Lawrence suggested that FHSC consider this as an additional PDL exception criteria adding that the other PDL exceptions are based on the physician's word.

Dr. Phillips requested that FHSC and DHCFP present a recommendation for any drug class where a patient has shown failure within the class, specifically the mental health class. This will be an agenda item for the next meeting.

IV. *Approval of Drug Classes to be Reviewed

A. October 2004
   1. Leukotriene Modifiers
   2. Antiemetics (oral)
   3. Inhaled Anticholinergics
   4. Erectile Dysfunction Agents

B. January 2005
   1. Serotonin Receptor Agonists (Triptans)
   2. Suggestions or requests from Committee

Motion: Dr. Horne motioned for approval of drug classes to be reviewed.
Seconded: Dr. Pinson
Ayes: Unanimous
Motion Carried.

V. Leukotriene Modifiers

Public Comment:
Dr. David Abramson, Merck, spoke in support of Singulair®.

Dr. Heard asked Dr. Abramson if he would recommend steroids be used first and either show failure or need for additional medication before this medication is used.

Dr. Abramson stated that it's appropriate to follow the national guidelines which recommend the first line of therapy be inhaled steroids and to work into the options for providing access to this class of drug if there is non-compliance or the steroids are not working.

Drug Class Review – First Health Services
Jamie Wyels, FHSC, presented an overview and comparison of the drugs within the class reviewed (attached) and recommended they be considered therapeutic alternatives.

Dr. Wiser asked if the National Asthma Guidelines are included in the review. The guidelines are not included in the review, but Mr. Wyels stated that the most recent National Asthma Guidelines by the National Asthma Education and Prevention Program and the National Heart Lung Blood Institute, state that leukotriene modifiers are an alternative option for patients with mal-persistent asthma and can also be utilized as an alternative option in combination with low to medium dose inhaled corticosteroids in moderate persistent asthma. They do not state preference from one agent over the other.

Committee Discussion and Action to Determine Clinical/Therapeutic Equivalency
Motion: Dr. Wiser motioned to accept these agents as therapeutic alternatives.
Seconded: Dr. Pintar seconded with a friendly amendment requesting consideration of the pediatric population as these agents have been efficacious in the younger than 5 age group and only one of these agents has that indication.
Amendment Accepted: Dr. Wiser
Ayes: Unanimous
Motion Carried

Presentation of Recommendations for PDL Inclusion by FHSC and the DHCFP
Dr. Monaghan stated that it is the recommendation of DHCFP and FHSC to add both Accolate® and Singulair® to the Preferred Drug List.

Committee Discussion and Approval of Drug for Inclusion in the PDL
Motion: Dr. Horne motioned to approve Accolate® and Singulair® to the PDL.
Seconded: Dr. Pinson

Ayes: Unanimous
Motion Carried

VI. Antiemetics (Oral)

Public Comment
Dr. Martha Joy, Glaxo Smith-Kline, expressed her support for the inclusion of Zofran® to the PDL.

Dr. Wiser asked if there were any head-to-head studies and if there are studies showing that the quick dissolving tablets are superior or more advantageous.

Dr. Joy: There are head-to-head studies with Anzemet® and Kytril®. As the first serotonin receptor antagonist on the market, Zofran® was the standard of comparison. There is comparison between Zofran® oral disintegrating tablet and the regular solid oral dosage form. Both are clinically equivalent as well as therapeutically and bioequivalent. For patients who are receiving radiation therapy and do not have enough saliva to take an oral solid dosage form, it presents an alternative.

Dr. Phillips asked for clarification on the statement regarding post-op vomiting and the three agents in terms of prevention and treatment and where Zofran® sits in that group.

Dr. Joy: Zofran® is indicated in the prevention of post-operative nausea and vomiting as well as Azemet® in contrast to Kytril®.

Dr. Phillips: Injectable Kytril® has FDA approval for that. The only one which has treatment for post-op is injectable Anzemet®.

Dr. Ken Romeo, Roche Laboratories, expressed support for the inclusion of Kytril® to the PDL (see attached handout).

.Dr. Romeo: Suggested focusing on the pharmacokinetics and dynamics of the drug. The CPY P450 system is not inhibited or induced in any manner. The conclusion being that other drugs will pass through freely, the patient is therefore safer.

Drug Class Review – First Health Services
Dr. Monaghan, FHSC, presented an overview and comparison of the drugs within the class reviewed (attached). There are currently three oral 5-HT_3 Receptor Antagonist available in the United States. None are available generically. All are FDA approved for chemotherapy- induced nausea and vomiting associated with moderately and highly emetogenic agents, and for the prevention of post-op nausea and vomiting. He stated that there are no significant differences in the antiemetic efficacy of these three agents and recommended they be considered therapeutic alternatives.

Dr. Heard: Why are we only considering orals when there are outpatient infusion chemotherapy centers?

Dr. Monaghan replied that injections typically are not billed through pharmacy claims but through clinics or physician offices.

Dr. Wiser suggested the adverse effect profile is a wash across the board and added that it's up to the clinicians to ensure that drug interactions are appropriately monitored and handled.

Committee Discussion and Action to Determine Clinical/Therapeutic Equivalency
Motion: Dr. Pinson moved to consider these agents as therapeutic alternatives.
Seconded: Dr. Wiser
Ayes: Unanimous
Motion Carried

Recommendations for Preferred Drug List (PDL) Inclusion
Dr. Monaghan stated that it is the recommendation of DHCFP and FHSC to add granisetron (Kytril®) to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Motion: Dr. Wiser moved to add granisetron (Kytril®) to the Preferred Drug List
Seconded: Dr. Pinson
Ayes: Unanimous
Motion Carried

VII. Inhaled Anticholinergics

Public Comment:
Dr. John Andrews, Pfizer, expressed support on behalf of Spiriva® (see attached handout).

Dr Wiser: has your company done the Phase IV Trials?

Dr. Andrews stated that Pfizer and Boehringer Ingleheim are co-promoting Spiriva® and are currently involved with putting together the Phase IV studies.

Drug Class Review – First Health Services
Dr. Monaghan, FHSC, presented an overview and comparison of the drugs within the class reviewed (attached). Both agents are FDA- approved for the treatment of bronchospasm associated with COPD and appear to be similar pharmacologically and reported incidence of adverse events. The most significant difference between these agents is the duration of the bronchodilator effect (ipratropium from 3-6 hours; tiotropium 24 hours or longer). Ipratropium has been available clinically since 1987. Tiotropium has been on the market since June 2004 (the side-effect profile and long term effect may not be fully realized). Dr. Monaghan recommended both agents be considered therapeutic equivalents.

Dr. Pintar expressed concern regarding use in the pediatric population. Only one of these drugs (Atrovent®) has a dosage form or mechanism of getting the drug into the pediatric population.

Dr. Heard commented that they do not seem to be alternatives if there is not an alternate form. He added that to his knowledge, Spirava® cannot be dissolved in a liquid for nebulizer delivery.

Committee Discussion and Action to Determine Clinical/Therapeutic Equivalency
Motion: Dr. Pintar moved to consider these agents therapeutically equivalent with availability of pediatric dosing form.
Seconded: Dr. Heard
Ayes: Unanimous
Motion Carried

Recommendations for Preferred Drug List (PDL) Inclusion
Dr. Monaghan stated that it is the recommendation of DHCFP and FHSC to add ipratropium bromide (Atrovent®), all dosage forms indicated, to the Preferred Drug List. He suggested that because tiotropium bromide is relatively new, consideration for PDL inclusion may be revisited in the future.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Motion: Dr. Wiser moved to add ipratropium bromide (Atrovent®) to the PDL
Seconded: Dr. Pinson
Ayes: Unanimous
Motion Carried

VIII. Erectile Dysfunction Agents

Public Comment:
Alan Christie, GSK, expressed support on behalf of Levitra.

At Dr. Wiser's request, Mr. Christie stated the reasons why Levitra should be the drug of choice: it works in the most difficult patients, high efficacy, safe, and shows positive data for men who are non-responsive to another PDE-5 inhibitor.

Dr. Gary Comstock, Pfizer, expressed support on behalf of Viagra (see attached handout).

Dr. Wiser: why do you think Viagra is the only PDE-5 inhibitor without the contraindication with alpha blockers?

Dr. Comstock: there are molecular and chemical differences in these medications that are clearly pointed out in non-industry studies.

At Dr. Wiser's request, Dr. Comstock stated the reasons why Viagra should be the primary drug: safety, efficacy and track record of use.

Dr. Pinson: is there any loss of integrity of the tablet if it is split?

Dr. Comstock: we are not aware that it does but do not recommend splitting.

Drug Class Review – First Health Services
Jamie Wyels, FHSC, presented an overview and comparison of the drugs within the class reviewed (attached). The three available agents in this class all appear to improve the quality and duration of erection. All appear to have similar contraindications, warnings, adverse drug events and drug interactions. None of these agents have shown to have one advantage over the other. Mr. Wyels recommended these agents be considered therapeutic alternates.

Committee Discussion and Action to Determine Clinical/Therapeutic Equivalency
Motion: Dr. Wiser moved to recommend these agents as therapeutic alternates.
Seconded: Dr. Pintar
Ayes: Unanimous
Motion Carried

Recommendations for Preferred Drug List (PDL) Inclusion
Dr. Monaghan stated that it is the recommendation of DHCFP and FHSC to add sildenafil (Viagra®) and vardenafil (Levitra®) to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Motion: Dr. Wiser to accept FHSC's recommendation.
Seconded: Dr. Horne
Ayes: Unanimous
Motion Carried

IX. Old Business

Discussion Regarding Provigil's Inclusion on the Preferred Drug List
Dr. Monaghan noted that this item is being revisited at the request of Dr. Horne.

Dr. Monaghan stated that a motion was made by Dr. Horne at the August 12th meeting to accept the recommendations of the stimulant ADHD drugs with the exception that Provigil be deleted from the non-preferred list. Dr. Heard made a friendly amendment to leave Provigil on the non-preferred list which Dr. Horne accepted and the votes were unanimous.

Dr. Horne requested that Provigil not be on the non-preferred list or allow use without a prior authorization for the FDA approved indications which do not include ADHD but is indicated for sleep disorders.

Dr. Heard requested medications used for sleep/wake cycles be considered at the next meeting. Dr. Phillips agreed and this item will be addressed at the January meeting.

X. **Review of January 27, 2005, Meeting Location, Date, and Time**

The next meeting is scheduled for January 27, 2005, location to be determined and announced.

XI. Public Comment

Bert Jones, GSK, stated that a ruling from his company's legal department stated written permission from the State was required to distribute documents promoting the PDL by pharmaceutical companies.

Coleen Lawerence, DHCFP, stated that she will consult with the deputy attorney general on how to proceed. In response to Dr. Horne's comments regarding accessibility to the PDL on-line, Ms. Lawrence stated that the web page is being redesigned for easy access to the PDL list in its entirety and will be available within a couple of months.

Dr. Pintar felt it would be appropriate to send the list in written form and Dr. Monaghan responded that the written list has been sent to all prescribers and added that FHSC can provide more copies, if needed.

Tom Wood, PhaRMA, stated that the OIG is demanding state review and ratification of promotional activities related to Medicaid approved drugs, including stickers on samples. In most cases, nothing should be promotional. Messages should be limited to drug availability only.

XII. *Adjournment

Motion: Dr. Heard motioned for adjournment.
Seconded: Dr. Pintar
Meeting Adjourned at 3:23 PM